REMARKS

Claims 28-36 and 40-42 are pending in the application. The amendment to the specification is to add the patent number of the parent application and to correct a typographical error in the filing date of the parent application. No new matter has been added. Applicant acknowledges the Examiner's statement that claims 28 and 29 are allowable.

Rejection under 35 U.S.C. § 102(e)

The Examiner rejected claims 30-32, 34-36, and 40-42 as anticipated by Fofonoff et al., (U.S. Pat. No. 5,911,942; "Fofonoff") under 35 U.S.C. § 102(e). The Examiner stated that Fofonoff teaches

> a process of making a biopolymer fiber as set forth in the instant claims (the laminar flow of coagulation fluid and the flow of biopolymer in Fofonoff et al. are horizontally directed as shown in Figure 1, and instant independent claim 30 is not limited to a particular direction; instant independent claim 28 is limited to vertically-directed flow).

This rejection is respectfully traversed. The claims are directed to methods for forming a fiber from a biocompatible biopolymer. The methods include the steps of creating a laminar flow of coagulation fluid having an upstream direction and a downstream direction, injecting a stream of biocompatible biopolymer into the downstream direction of the laminar flow of coagulation fluid, the stream being injected so as to be surrounded by coagulation fluid and propelled into the downstream direction by the laminar flow of coagulation fluid, and allowing the coagulation fluid to coagulate the biopolymer stream, thereby forming a biopolymer fiber.

One element of the rejected claims is that they include the step of using laminar flow of coagulation fluid for producing a biopolymer fiber. Laminar flow is defined on page 2, lines 31-32, of the specification where it states that "as used herein, 'laminar flow' refers to uniform laminar flow in which the velocity profile of the flow is symmetric about the tube axis." An advantage of generation of fibers in a laminar flow is noted on page 3, lines 5-10, of the specification where it states that "as a result of the laminar flow, no significant transverse forces disturb the coagulating fiber...because the fiber is relatively free of any mechanical stresses

during its formation, very long and fine fibers approaching the dimensions and strengths of *in vivo* fibers can be readily produced."

Methods by which one can achieve laminar flow in producing biopolymer fibers and the desirability of using laminar flow are discussed throughout the present specification. For example, on page 5, lines 1-3, it is noted that, in using an apparatus for producing biopolymers, "since fluid flow is generally laminar immediately adjacent to a surface such as the inner wall **18** [element **18** of Figure 2], it is preferable to select the diameter of the bore **20** to be small enough to enhance the likelihood of laminar flow throughout its cross-section." Further guidance for producing biopolymers in apparati in which the flow of coagulation fluid is laminar is provided, e.g., on page 8, lines 22-29, where it states that "the laminar flow of coagulation fluid in the fiber-formation tube **12** reduces the likelihood of the above-mentioned risks [of mechanical stress on the fiber] by reducing the likelihood that the fiber will contact the inner wall **18** of the fiber-formation tube **12**. This occurs because the fiber will naturally follow the streamlines of the flow in which it is placed. Since the streamlines in laminar flow are parallel to the inner wall **18**, and since the stream of liquid biopolymer is introduced along the axis **X** of the fiber-formation tube **12**, the laminar flow in the bore **20** will tend to maintain the fiber collinear with the axis **X** of the fiber-formation tube **12** and away from the inner wall **18**. This results in fiber having a circular cross-section and minimal surface imperfections."

Contrary to the Examiner's assertion, Fofonoff does not disclose methods of forming a biopolymer fiber in a laminar flow of coagulation fluid. The statement that "the opening of spinneret [through which the biopolymer fluid is extruded] is immersed in a flowing coagulation solution **20**" (col. 3, lines 8-9) fails to disclose Applicant's claimed feature; that the coagulation fluid is "flowing" is not a disclosure that the flow is laminar. Applicant's methods define laminar flow as flow in which the velocity profile is symmetric about the axis of a tube. Fofonoff does not disclose a method (or a rationale) for producing a biopolymer in a laminar flow of coagulation fluid. For example, Fofonoff does not require or prefer the use of a tube for containing the flowing coagulation fluid, as evidenced, e.g., by the passage in column 2, lines 15-17, which states: "Coagulation bath **18** allows collagen gel **22** fiber to be formed in a

horizontal trough or in a tube or vertically in a tube." A trough is suitable for Fofonoff's methods, yet achieving laminar flow in a trough is more complicated than achieving laminar flow in a tube, in which the walls may impact the velocity of flowing liquid symmetrically about the axis of the tube. The reference fails to describe how one would create laminar flow of a fluid in a tube or a trough.

One means by which laminar flow can be achieved includes use of a fiber formation tube with a small bore. Fofonoff is silent with respect to such methods and the advantages of their use. For example, Fofonoff indicates that the fiber formation tube (which Fofonoff refers to as the "coagulation bath") be "suitably sized for allowing extrusion of fiber from spinneret **16** through coagulation solution **20** while having a sufficient residency time for collagen gel fiber **22** to form" (column 3, lines 10-12). Fofonoff's guidance for the size of the coagulation bath lacks consideration of the parameters needed to achieve laminar flow.

As discussed above, the present specification discloses advantages of using laminar flow that include the ability to produce fibers that are long, fine, and exposed to minimal mechanical stresses during formation. Another advantage of the use of laminar flow is that it allows one to use a narrow fiber-formation tube which requires less coagulation fluid. As noted in the specification, "it is economically feasible to discard coagulation fluid after a single use and to use only fresh coagulation fluid during the fiber-formation process. This enables the resulting fiber to be more readily make aseptic and, therefore, more suitable for use in a patient" (page 3, lines 12-15). Additional advantages of the claimed methods include, for example, an increased ability to regulate pH of the coagulation fluid (see, e.g., page 10, lines 2-4), the ability to use low-viscosity coagulation fluids (see, e.g., page 10, lines 6-7), and an ability to increase the rate of fiber formation (see, e.g., page 10, lines 19-24). The cited reference does not disclose the use of laminar flow explicitly or inherently. Furthermore, the advantages of using laminar flow for fiber formation are not disclosed. Thus, Fofonoff does not anticipate the claims.

Applicant respectfully asks that the rejection of claims 30-32, 34-36, and 40-42 under 35 U.S.C.§ 102(e) be withdrawn. Applicant asks that the objection to claim 33 as dependent on a

rejected base claim (claim 30) also be withdrawn in view of the foregoing discussion of the patentability of claim 30.

Enclosed are checks for the Petition for Extension of Time fee and the Information Disclosure Statement. Please apply any other charges or credits to deposit account 06-1050, with reference to Attorney Docket No. 13343-004002.

Respectfully submitted,

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The Drawings

In the Office Action mailed February 17, 2004, the Examiner stated that the drawings were missing from the file. Copies of the drawings are provided herewith.